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Proposed Registration Decision PRD2015-23

Mono- and Di-potassium Salt of Phosphorus Acid (Rampart)

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Overview

Proposed Registration Decision for Mono- and Di-Potassium Salts of Phosphorous Acid

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Rampart Technical and Rampart Fungicide, containing the technical grade active ingredient mono- and di-potassium salts of phosphorous acid, to suppress downy mildew in greenhouse cucumbers.

Rampart Technical (Registration Number 30653) and Rampart Fungicide (Registration Number 30654) are fully registered for use in Canada on certain field grown vegetables and fruit, as well as for post-harvest treatment on stored potatoes. The original review for Rampart Technical and Rampart Fungicide can be found in Proposed Registration Decision PRD2012-26, *Mono- and Di-Potassium Salts of Phosphorous Acid (Rampart)* and Registration Decision RD2013-05, *Mono- and Di-Potassium Salts of Phosphorous Acid (Rampart)*. The active ingredient, mono- and di-potassium salts of phosphorous acid, is fully registered for use in greenhouses in Canada, however, the current applications represent a major new use in greenhouses for this source of the active ingredient.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Rampart Technical and Rampart Fungicide.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "... the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on mono- and di-potassium salts of phosphorous acid, the PMRA will consider any comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on mono- and di-potassium salts of phosphorous acid, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What Is Mono- and Di-Potassium Salts of Phosphorous Acid?

Mono- and di-potassium salts of phosphorous acid (commonly known as phosphorous acid) are phosphonate fungicides belonging to the Group 33 class of fungicides as designated by the Fungicide Resistance Action Committee. It may inhibit the metabolism of susceptible fungal pathogens, and stimulate the plant's natural defence response to pathogen attack. Mono- and di-potassium salts of phosphorous acid are currently registered in Canada as a foliar fungicide on certain vegetables and fruits, and a post-harvest treatment on stored potatoes.

Health Considerations

Can Approved Uses of Mono- and Di-Potassium Salts of Phosphorous Acid Affect Human Health?

Mono- and di-potassium salts of phosphorous acid is unlikely to affect human health when used according to label directions.

Exposure to mono- and di-potassium salts of phosphorous acid may occur when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

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3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Mono- and di-potassium salts of phosphorous acid are of low acute toxicity, irrespective of the route of exposure, and mildly irritating to the eyes. The precautionary label statement indicating that contact with skin, eyes, and clothing must be avoided, and the personal protective equipment statement that applicators and other handlers must wear a long-sleeved shirt, long pants, gloves, shoes plus socks, and protective eyewear are effective mitigative measures to reduce the risk associated with the use of mono- and di-potassium salts of phosphorous acid.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Dietary risk to humans is considered negligible based on a long history of use and the low toxicity of the end-use product. The available literature suggests that there is no toxicological concern from ingestion of the end-use product residues.

It is anticipated that the use of mono- and di-potassium salts of phosphorous acid in Canada on greenhouse cucumber will not pose a risk to any segment of the population, including infants, children, adults and seniors, from consumption of produce from treated crops. The end-use product is registered for field uses in Canada to suppress downy mildew in brassica leafy vegetables, grapes and blackberry, as well as for field use and post-harvest storage treatment to suppress late blight and pink rot in potatoes. PMRA did not specify MRLs (maximum residue levels) for mono- and di-potassium salts of phosphorous acid for the registered field uses.

No risk due to exposure from drinking water is anticipated as the end-use product is proposed for greenhouse application.

Risks in Residential and Other Non-Occupational Environments

Estimated risk for residential and other non-occupational environments is not of concern.

Risk to people from residential and other non-occupational environments is not expected as the proposed new use is for greenhouse application, and due to the low toxicity of mono- and di-potassium salts of phosphorous acid.

Occupational Risks From Handling Rampart Fungicide

Occupational risks are not of concern when Rampart Fungicide is used according to the label directions, which include protective measures.

Precautionary (for example, wearing of personal protective equipment) and hygiene statements on the label are considered adequate to protect individuals from occupational exposure. Since the application is done in a greenhouse by commercial applicators, exposure to bystanders is expected to be negligible.

Environmental Considerations

What Happens When Mono- and Di-Potassium Salts of Phosphorous Acid Is Introduced Into the Environment?

Mono- and di-potassium salts of phosphorous acid are not expected to pose an unacceptable risk to the environment when used according to label directions as a fungicide in a greenhouse.

Mono- and di-potassium salts of phosphorous acid can enter the environment when Rampart Fungicide is used as a foliar-spray for food crops in greenhouses. Overall inputs to soil and water are considered to be less than the currently registered agricultural applications of this pesticide (in other words, field crops).

Mono- and di-potassium salts of phosphorous acid are not expected to pose an unacceptable risk to non-target terrestrial and aquatic species from use in greenhouses. This is based on the low toxicity to tested organisms and because environmental exposure is expected to be limited from use in greenhouses.

Value Considerations

What Is the Value of Rampart Fungicide

Mono- and di-potassium salts of phosphorous acid, the active ingredients in Rampart Fungicide, suppress downy mildew in greenhouse cucumbers.

Rampart Fungicide, containing mono- and di-potassium salts of phosphorous acid, has previously demonstrated to be effective against certain pathogens that cause downy mildew on brassica leafy vegetables, grapes and blackberry. It has now been demonstrated to suppress downy mildew on greenhouse cucumbers, which is an important disease to manage in greenhouse production. Certain conventional and non-conventional fungicides are registered on greenhouse cucumbers to control or suppress downy mildew. The registration of Rampart Fungicide adds an additional non-conventional product which will contribute to the disease management options for downy mildew for greenhouse cucumber growers, and a rotational alternative, which contributes to resistance management. Rampart Fungicide can also be easily integrated into existing integrated pest management programs on greenhouse cucumbers.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Rampart Fungicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Although the toxicological profile of the end-use product raises no major hazards of concern, to ensure bystander protection and mitigate postapplication exposure of workers, the end-use product label is required to include the precautionary statements, "Keep unprotected persons out of the treated areas in a greenhouse for the duration of the treatment period" and "Allow entry or re-entry to greenhouse only after thorough ventilation and spray mist has cleared and the treated surface has dried."

Environment

Precautionary label statements that are required for all commercial products will be required.

Next Steps

Before making a final registration decision on mono- and di-potassium salts of phosphorous acid, the PMRA will consider any comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on mono- and di-potassium salts of phosphorous acid (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Mono- and di-potassium salts of phosphorous acid

The original review for Rampart Technical and Rampart Fungicide can be found in Proposed Registration Decision PRD2012-26, Mono- and Di-Potassium Salts of Phosphorous Acid (Rampart) and Registration Decision RD2013-05, Mono- and Di-Potassium Salts of Phosphorous Acid (Rampart).

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance		
Function	Fungicide	
Chemical name		
1. International Union of Pure and Applied Chemistry (IUPAC)	Monopotassium phosphonate and Dipotassium phosphonate	
2. Chemical Abstracts Service (CAS)	Phosphonic acid, monopotassium salt and Phosphonic acid, dipotassium salt	
CAS number	Monopotassium phosphonate Dipotassium phosphonate	13977-65-6 13492-26-7
Molecular formula	Monopotassium phosphonate Dipotassium phosphonate	K_2HPO_3, K_2HPO_3,
Molecular weight	Monopotassium phosphonate Dipotassium phosphonate	120.09 158.19
Structural formula		
	13977-65-6	13492-26-7
Purity of the active ingredient	53%	

8.2 Physical and Chemical Properties of the Active Ingredient and End-Use Product

Technical Product – Rampart Technical

Property	Result
Colour and physical state	Colourless liquid
Odour	Odourless
Melting range	Not applicable
Boiling point or range	100 °C
Density	1.01 g/mL
Vapour pressure	The product is an aqueous liquid
Ultraviolet (UV)/visible spectrum	The product is not likely to absorb at > above 100 nm
Solubility in water	Miscible
Solubility in organic solvents	Insoluble in most organic solvents
n-Octanol/water partition coefficient (K_{OW})	Not applicable. The product is available in ionized
Dissociation constant (pK_a)	The mono- and di-potassium phosphites are essentially completely dissociated in aqueous solution
Stability (temperature, metal)	Is unable to metal and metal ions (iron powder, ferric chloride, lead dust and lead nitrate)

End-Use Product – Rampart Fungicide

Property	Result
Colour	Colourless
Odour	Odourless
Physical state	Liquid
Formulation type	Solution
Guarantee	20 %
Container material and description	HDPE plastic jug, bulk size from 3.8L to 1000L
Density	1.01 g/mL
pH of 1% dispersion in water	6.7
Oxidizing or reducing action	The product is neither an oxidant nor a reductant
Storage stability	Is unable to metal and metal ion (iron powder, ferric chloride, lead dust and lead nitrate). The product is packaged in HDPE plastic containers and is expected to be stable.
Corrosion characteristics	The product is not expected to be corrosive
Explodability	The product is not expected to be explosive

8.3 Directions for Use

Use suppress downy mildew on greenhouse cucumbers, make foliar applications of Rampart Fungicide at 3 – 5 L/ha with a two to four week interval. A maximum of six applications is permitted per crop cycle in the greenhouse.

1.4 Mode of Action

Mono- and di-potassium salts of phosphorous acid are phosphonate fungicides that have a direct effect by inhibiting metabolism of susceptible fungal pathogens, especially in the class of oomycetes, and an indirect effect by stimulating the plant's natural defence response to pathogen attack.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The methods previously provided for the analysis of the active ingredient and the impurities in Rampart Technical have been validated and assessed to be acceptable for the determinations.

2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredient in the formulation has been validated and assessed to be acceptable for use as an enforcement analytical method.

3.0 Impact on Human and Animal Health

3.1 Toxicological Summary

Please refer to PRD2013-20 and RD2015-09 for a detailed summary of the toxicology of the Rampart Technical and Rampart Fungicide.

Incident Reports

Since 26 April 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on the Health Canada website. Incidents from Canada were searched for pesticide products containing the active ingredient mono- and di-potassium salts of phosphorous acid.

As of 29 November 2016, the PMRA received one human incident report, which was presented in the previous publication document (PRD2013-20).

3.2 Occupational and Bystander Exposure and Risk Assessment

3.2.1 Dermal Absorption

Dermal exposure is expected to be minimal due to the use pattern of the product and the method of application. Since the available literature suggests a negligible dermal absorption of mono- and di-potassium salts of phosphorous acid, and since adequate precautionary and hygiene

statements are currently on the product label, a dermal absorption study was not considered necessary to complete the health hazard assessment of mono- and di-potassium salts of phosphorous acid.

3.2.2 Mixer, Loader, and Applicator Exposure and Risk

Occupational exposure to the mixer, loader, and applicator, as well as those responsible for clean-up and maintenance activities, is anticipated to be minimal. Workers will be primarily exposed by both inhalation and dermal routes. Ocular exposure is also possible from splash during handling or from exposure to spray drift during application. Applicator exposure is of concern mainly when Rampart Fungicide is applied as a foliar spray using boom sprayers.

The Rampart Fungicide label has a number of exposure reduction statements (for example, wearing of personal protective equipment, clothing, hygiene statement) to protect mixers, loaders and applicators against any unnecessary risk from exposure. The label instructs that applicators and other handlers must wear protective eyewear, long pants and long sleeved shirt, waterproof gloves, and shoes plus socks; also, avoid breathing of vapours or spray mist, avoid contact with eyes, skin or clothing; remove contaminated clothing and wash clothing before reuse, which should be effective in minimizing the potential for exposure.

Significant risk from exposure to mono- and di-potassium salts of phosphorous acid for the mixer, loader and applicator, as well as those responsible for clean-up, maintenance and repair activities, is not anticipated due to the low toxicity of the active ingredient and reduced occupational exposure when label directions are followed.

3.2.3 Postapplication Exposure and Risk

Postapplication exposure is possible when workers enter the treated area in the greenhouse soon after the application, and it is of concern when such exposure happens without adequate protection. The primary exposure routes for re-entry workers/individuals are dermal, from contact with freshly treated surfaces, as well as ocular and inhalation exposures to spray mist if the area is not thoroughly ventilated or sufficient time was not given to let the suspended particles settle out of the air. Exposure may result in irritation to the eyes and the respiratory tract.

To ensure protection from postapplication exposure, restricting entry/re-entry of workers into the greenhouse until the area is thoroughly ventilated, for suspended particles to settle, and treated surfaces are dried, are required as precautionary measures.

3.2.4 Residential and Bystander Exposure and Risk

No residential exposure is expected from the proposed new uses. As the commercial application in the greenhouse involves only authorized personnel, bystander exposure is expected to be negligible when Rampart Fungicide is used according to the label directions.

3.3 Food Residue Exposure Assessment

3.3.1 Food and Drinking Water

Rampart Fungicide is to be used for treating greenhouse cucumber for suppression of downy mildew. The greenhouse use pattern is similar to the existing registered field uses of Rampart Fungicide for suppression of downy mildew; therefore, a further assessment of food residue exposure is not required.

Refer to PRD2012-26 and RD2013-05 for details related to the food residue exposure assessment of both the technical product and the end-use product.

As the new use is for greenhouse application and Rampart Fungicide is not to be applied near or directly to water, residues in drinking water are not anticipated.

3.3.2 Maximum Residue Limits (MRLs)

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine that the consumption of the maximum amount of residues that are expected to remain on food products when a pesticide is used according to label directions will not be a concern to human health. This maximum amount of residues expected is then legally specified as a maximum residue limit (MRL) under the *Pest Control Products Act* for the purposes of adulteration provision of the *Food and Drugs Act*. Health Canada specifies science-based MRLs to ensure the food Canadians eat is safe.

PMRA did not specify an MRL for mono- and di-potassium salts of phosphorous acid for the registered field uses. Since the greenhouse use is not likely to increase human dietary exposure to mono- and di-potassium salts of phosphorous acid, an MRL is not specified for the greenhouse use.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

For more information on the fate and behaviour of Rampart Technical and Rampart Fungicide in the environment, see PRD2012-26 and RD2013-05.

4.2 Environmental Risk Characterization

As for other uses, toxicity information for beneficial arthropods is requested for greenhouse use because bees and predatory and parasitic insects are often used in greenhouses for pollination and pest control services, respectively. As Rampart Technical and Rampart Fungicide are currently registered for field use on brassica leafy vegetables (Crop Group 5), grapes and blackberry, as well as for control of late blight and pink rot on stored potatoes, information on the toxicity to insects (honeybees) has been assessed in the original review (see PRD2012-26)

and showed that mono- and di-potassium salts of phosphorous acid are practically non-toxic to beneficial insects. Some exposure of aquatic systems may occur from greenhouses through disposal of wastewaters. However, based on previously submitted studies (see PRD2012-26), mono- and di-potassium salts of phosphorous acid demonstrates low toxicity to aquatic organisms.

A qualitative risk assessment was conducted for the use in greenhouses. Although the maximum application rate for greenhouse use (up to 8 L/ha equivalent to 42.4 g a.i./ha) is slightly higher than field use (up to 7 L/ha equivalent to 37.1 g a.i./ha), the exposure of non-target organisms in the environment to mono- and di-potassium salts of phosphorous acid is expected to be limited with greenhouse use when compared to field uses. Also, based on the low toxicity of mono- and di-potassium salts of phosphorous acid demonstrated to tested species, and the limited exposure following its use in a greenhouse, the risk to beneficial insects and to aquatic organisms is expected to be negligible.

5.0 Value

5.1 Consideration of Benefits

Downy mildew is a common disease in the greenhouse where ventilation is inadequate and humidity is high. It is a serious threat to the greenhouse cucumber industry. In order to manage the disease effectively, growers need to carefully select fungicidal products with consideration of disease resistance management. Phosphorous acid is a non-conventional fungicide with a low risk of resistance development. The registration of this use of Rampart Fungicide provides Canadian growers with an additional product in the market to manage the disease in greenhouse cucumbers.

A number of conventional and non-conventional fungicides are registered on both field and greenhouse cucumbers to control or suppress downy mildew. Refer to Appendix 1, Table 1, for further information on alternative products.

Multiple alternative products with different modes of action are already registered for downy mildew in greenhouse cucumbers, including various phosphorous acid fungicides. The risk of disease resistance development to Rampart Fungicide is not considered a major concern in the greenhouse cucumber production.

The use of Rampart Fungicide will contribute to the management of downy mildew on greenhouse cucumbers. Rampart Fungicide would be a good addition to integrated pest management programs on greenhouse cucumbers, complementing the microbial agents and serving as a good rotational partner to conventional fungicides.

5.2 Effectiveness Against Pests

Use of phosphorous acid for suppression of downy mildew on cucurbits (including cucumber) is currently registered in Canada in two similar end-use products. In addition, Rampart Fungicide is

registered in Canada for suppression of downy mildew on brassica leafy vegetables, grapes and blackberry. Use history information from a commercial greenhouse in the United States also indicated that Rampart Fungicide suppressed downy mildew on greenhouse cucumbers after two applications in most cases. Therefore, based on precedent registrations and use history information for this specific use, the registration is supported.

5.3 Non-Safety Adverse Effects

No phytotoxicity or crop injury was reported in published literature and use history information cited.

5.4 Supported Uses

A use claim of Rampart Fungicide for suppression of downy mildew on greenhouse cucumbers is supported according to the use directions provided.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, in other words, persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic, as defined by the *Canadian Environmental Protection Act*].

During the review process, mono- and di-potassium salts of phosphorous acid were assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

Mono- and di-potassium salts of phosphorous acid do not meet Track 1 criteria, and are not considered Track 1 substances. They are inorganic substances and are not expected to bioaccumulate in the environment.

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[5] DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*.[6] The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations including: DIR99-03; and DIR2006-02[8], and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- Technical grade mono- and di-potassium salts of phosphorous acid (Rampart Technical) and the end-use product Rampart Fungicide do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

7.0 Summary

7.1 Human Health and Safety

The toxicology profiles of Rampart Technical and Rampart Fungicide are as characterized before. They are of low acute toxicity irrespective of the route of exposure and mildly irritating to the eyes.

Although occupational exposure is expected, the precautionary statements on the Rampart Fungicide label are sufficient to minimize any risk due to exposure of workers and bystanders.

Exposure to mono- and di-potassium salts of phosphorous acid from the diet or drinking water is not expected to be of concern. The PMRA did not specify an MRL for mono- and di-potassium salts of phosphorous acid.

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6 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

7 NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.*

8 DIR2006-02, *Formulants Policy and Implementation Guidance Document.*

7.2 Environmental Risk

The use of Rampart Technical as a fungicide in greenhouses, according to the label of Rampart Fungicide, is expected to pose a negligible risk to terrestrial or aquatic non-target organisms.

7.3 Value

The active ingredient of Rampart Fungicide, mono- and dipotassium salts of phosphorous acid, is effective to manage diseases caused by organisms that belong to the oomycetes, including causal pathogens of downy mildew, on a number of crops. It is a non-conventional fungicide with a low risk of resistance development. The registration of this use of Rampart Fungicide provides Canadian growers with an additional product in the market to manage the disease in greenhouse cucumbers. It will also add a rotational alternative, which contributes to resistance management. Rampart Fungicide can be easily integrated into existing integrated pest management programs on greenhouse cucumbers.

Based on the value information provided, the registration of Rampart Fungicide to suppress downy mildew on greenhouse cucumbers is supported.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Rampart Technical and Rampart Fungicide, containing the technical grade active ingredient mono- and di-potassium salts of phosphorous acid, to suppress downy mildew in greenhouse cucumbers.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

λ	wavelength
℃	degrees Celsius
a.i.	active ingredient
CAS	Chemical Abstracts Service
DACO	data code
DIR	Regulatory Directive document
FRAC	Fungicide Resistance Action Committee
g	gram(s)
ha	hectare(s)
HDPE	High Density Polyethylene
IUPAC	International Union of Pure and Applied Chemistry
K_{ow}	*n*-octanol-water partition coefficient
L	litre(s)
mL	millilitre(s)
MRL	maximum residue limit
NC	Not Classified
nm	nanometre(s)
NOI	Notice of Intent document
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
PRD	Proposed Registration Decision document
RD	Registration Decision document
TSMP	Toxic Substances Management Policy
USA	United States of America
UV	ultraviolet

Appendix I Tables and Figures

Table 1 Registered Alternatives in Canada for use on cucumbers (both field and greenhouse) as of March 2015

Disease	Active ingredient (FRAC Fungicide Group)
Downy mildew (*Pseudoperonospora cubensis*)	Amectoctradin (45) Amectoctradin (45) + dimethomorph (40) *Bacillus subtilis* strain QST 713 (44) (Suppression)* Chlorothalonil (M5) Citric acid + lactic acid (NC) (Suppression)* Copper (M3) Cyazofamid (21) Dimethomorph (40) (Suppression) Fenamidone (11) Fluopicolide (43) Folpet (M4) Garlic powder (NC) (May inhibit symptoms)* Mancozeb (M3) Mandipropamid (40) (Suppression) mono- and di-basic sodium, potassium and ammonium phosphites (33) (Suppression)* Mono- and di-potassium salts of phosphorous acid (33) (Suppression)* Propamocarb (28) (Suppression) Propamocarb (28) + chlorothalonil (M5) Pyraclostrobin (11) Tea tree oil (NC) (Suppression)*

* Non-conventional product.

Table 2 Supported Use

Proposed claim	Accepted claim
Control of downy mildew on greenhouse cucumber at rates of 3.0 to 8.0 L of Rampart Fungicide in 1000L of water per ha. Apply the lower rate at 2- to 4-week intervals after plants become established in a **Disease prevention program**. Apply higher rate at 2- to 3- week intervals until control is reached in a **Disease control program**. Do not apply Rampart Fungicide at intervals less than 3 days.	Suppression of downy mildew (*Pseudoperonospora cubensis*) on greenhouse cucumber: Make foliar applications of Rampart Fungicide at a rate of 3 – 5 L/ha. Begin applications after plants become established. Apply at 2 – 4 week intervals, using the higher rate and shorter interval when disease pressure is severe. The suggested water volume is 1000 L/ha when cucumber plants are of medium size. DO NOT make more than six applications per crop cycle in the greenhouse.

References

A. List of Studies/Information Submitted by Registrant

1.0 Human and Animal Health

PMRA Document Number	Reference
2389563	Use Description / Exposure Scenarios, DACO 5.2
2520992	Use Description / Exposure Scenarios, DACO 5.2

2.0 Environment

PMRA Document Number	Reference
2011309	2010, Summary – Environmental Toxicology, DACO 9.1, 9.2.1, 9.3.1, 9.5.1, 9.6.1, 9.8.1, 9.8.5, 20140424 APPL 9.1, 9.2.1, 9.3.1, 9.5.1, 9.6.1, 9.8.1, 9.8.5

3.0 Value

PMRA Document Number	Reference
2389549	2014, Efficacy and Crop Tolerance of Rampart™ Fungicide Reg. No 30654 (Active ingredient Mono- and Dipotassium Salts of Phosphorous Acid) Powdery Mildew, Downy Mildew, *Phytophthora*, *Pythium* and *Fusarium* on Greenhouse Cucumbers, Lettuce and Crop Group 8 (Peppers, Tomatoes, Eggplants), DACO 10.1
2430032	2014, Value: Registration of Rampart (Mono- and Dipotassium Salts of Phosphorous Acid, PCP No. 30654) for the Control of *Pythium*, *Fusarium* and Downy Mildew on Greenhouse Cucumbers, DACO 10.1
2430033	2014, Use History, DACO 10.2.4